

Committee on Ways and Means

U.S.-Morocco FTA: Pharmaceutical Test Data Protection

- The FTA prohibits the use by third persons of another person's test data to obtain approval for generic drugs for five years.
- However, the agreement explicitly states that this limitation does not apply in certain circumstances. Specifically, the agreement allows Morocco to take necessary measures to protect public health by promoting access to medicines for all, in particular for epidemics as well as circumstances of extreme urgency or national emergency.
- While in certain cases the short term effect of the 5-year limitation on test data could mean that certain other generic drugs may not be immediately approved, the practical effect should be to improve access to drugs.
 - Under the status quo, U.S. drug companies are reluctant to provide drugs to Morocco because as soon as a drug is sold in Morocco, the test data is not protected.
 - Data protection will provide an incentive to bring innovative drugs to the Moroccan market, and after five years, test data used to certify an innovative drug can be used to approve a generic version.
 - Such a policy balances the need to provide incentives to innovators with the needs of developing countries to use test data to certify generics.
 - Since the Jordan free trade agreement, which contains a similar provision, went into effect in 2000, 32 new innovative drugs have obtained marketing approval, a significant increase over pre-Agreement approvals.
- This provision reflects U.S. domestic practice and standards. The bipartisan negotiating objectives in TPA direct USTR to persuade other countries to commit to U.S. practice and standards for the protection of intellectual property.
- In addition, the principle of protecting data against unfair commercial use is enshrined in the WTO, of which Morocco is a member, so limiting proprietary data from being immediately available to certify a generic drug is not unreasonable. In fact, the EU imposes a requirement of up to ten years.
- Not only is the protection of data part of U.S. law, but provisions protecting test data have appeared in the intellectual property chapter of every free trade agreement the United States has negotiated, including the NAFTA and the agreements with Jordan, Chile, Singapore, and Australia. The inclusion of this provision in the Morocco agreement does not break new ground.

PROCESS ARGUMENTS

- Text including this provision as part of the U.S. negotiating proposals was provided to cleared staff on March 13, 2003, well over one year ago. In the past year, USTR has had numerous consultations on the free trade agreement with Morocco, including the intellectual property provisions, and this issue was not raised until recent weeks.
- The purpose of the consultation period is to allow concerns to be addressed during the negotiations. It is difficult to address these concerns once a carefully crafted agreement has been signed between the parties.